5.0 510(k) Summary of Safety and Effectiveness

Product: ***Bard® DigniCare Stool Management System***

JUN 13 2008

Submitter's Information:

Michelle Gudith
Director, Regulatory Affairs
Bard Medical Division
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8195 Industrial Blvd.
Covington, Georgia 30014 USA
Phone (770) 784-6722, Fax (770) 385-4768
E-mail michelle.gudith@crbard.com

Date Prepared: December 12, 2007

Name of Device and Name/Address of Sponsor:

Bard® DigniCare Stool Management System

C.R. Bard Inc.
Bard Medical Division
8195 Industrial Blvd.
Covington, Georgia 30014 USA
Phone (770) 784-6722, Fax (770) 385-4768

COMMON OR USUAL NAMES

Rectal catheter

CLASSIFICATION NAME

Gastrointestinal tube and accessories

PREDICATE DEVICES

K032734 Convatec Fecal Management System

K023344 Indwelling Fecal Management System

K073598
2 of 3

INTENDED USE AND INDICATIONS FOR USE

The *Bard® DigniCare Stool Management System* is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients.

Adult Use Only

TECHNOLOGICAL CHARACTERISTICS

The device is composed of a catheter which consists of a retention cuff, a trans-sphincteric zone and a drainage tube. In addition, the system contains a collection bag, a syringe, lubricating jelly, an underpad and a biological odor eliminator.

The catheter is connected to a collection bag. When the catheter is disengaged from the bag, the catheter automatically closes to prevent leakage. A plug is placed on the collection bag to contain the fecal matter within the bag.

The device is single-use and latex-free

PERFORMANCE DATA

Functional, biocompatibility and predicate device comparative testing have demonstrated that the subject device is as safe and effective as the predicate devices.

SUBSTANTIAL EQUIVALENCE

The ***Bard® DigniCare Stool Management System*** is as safe and effective as the predicate devices with the same intended use, similar indications, technological characteristics, and principles of operation. The technological differences between the subject device and its predicate devices raise no new issues of safety or effectiveness. Therefore, the ***Bard® DigniCare Stool Management System*** is substantially equivalent to currently marketed fecal management systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2008

Ms. Michelle Gudith
Director, Regulatory Affairs
Bard Medical Division
C.R. Bard, Inc.
8195 Industrial Blvd.
COVINGTON GA 30014

Re: K073598
Trade/Device Name: *Bard® DigniCare Stool Management System*
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: April 14, 2008
Received: April 15, 2008

Dear Ms. Gudith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

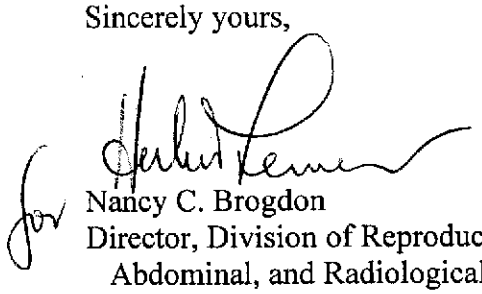
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh.dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K073598

Indications for Use Statement

510(k) Number (if known): K073598

Device Name: ***Bard® DigniCare Stool Management System***

Indications for Use: The ***Bard® DigniCare Stool Management System*** is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients.

Adult Use Only

Prescription Use: X AND/OR Over-the-Counter Use: _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073598